
K093251

OCT 29 2009

# 510(k) Summary

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| **Submitter:** | OmniGuide, Inc.<br>One Kendall Square, Building 100 3rd Floor<br>Cambridge, MA 02139 |
| **Contact Person:**<br>**Telephone:** | Douglas W. Woodruff<br>617-551-8404 |
| **Fax:** | 617-551-8445 |
| **Proprietary Name:** | OmniGuide BeamPath® FELS 25A, $CO_2$ Laser System |
| **Common Name:** | $CO_2$ Laser Powered Surgical Instrument |
| **Classification:** | 878.4810 |
| **Product Code:** | GEX |
| **Classification Name:** | Laser surgical instrument for use in general and plastic surgery and in dermatology. |

**Substantial Equivalence Claimed To:**

K063698 C-Las $CO_2$ Laser System

**Description:**

The OmniGuide BeamPath FELS 25A, $CO_2$ Laser System, is a Carbon dioxide ($CO_2$) Laser emitting light at a wavelength of 10.6 μm. It has an RF excited laser tube which produces a maximum continuous wave (CW) output power of up to 30 watts. Laser energy ($CO_2$), with a wavelength of 10.6 μm, has a variety of attractive features for surgical use. Because it is strongly absorbed by water (the main constituent of biological tissue) it does not penetrate into tissue beyond the point of application of the laser energy. This small depth of penetration (0.1-0.2 mm) leads to high cutting precision and minimal thermal damage to adjacent tissue. In addition, the $CO_2$ wavelength has excellent coagulation capabilities

The laser console is a table top console which can be easily transported from one surgery room to the other. The controls for the physician are part of the console and the parameters are clearly displayed on a large screen display. The laser light is guided through different mirrors and focused via an attached adapter. The adapter is the interface allowing an OmniGuide BeamPath Fiber or equivalent to attach to the laser.

Materials used are mainly machined aluminum or stainless Steel and standard optics for the transmission or the reflection of the $CO_2$ laser wave length. Only the laser energy from the OmniGuide BeamPath FELS 25A, $CO_2$ Laser System comes in contact with the patient. The energy is guided through a hollow waveguide such as the OmniGuide BeamPath hollow waveguide fiber. It is worth noting that all components (mirrors, lenses and the fiber) that the CO2 light travels though are passive and do not alter the wavelength or any other of the fundamental properties or beneficial attributes of the CO2 Laser.

**Indications for Use:**

The OmniGuide BeamPath FELS 25A, $CO_2$ Laser System is indicated for the incision, excision, ablation, vaporization and coagulation of body soft tissues in the following specialties:

- Dermatology
- General Surgery
- Gynecology
- Head & Neck Surgery
- Neurosurgery
- Oral Surgery
- Orthopedic Surgery
- Otorhinolaryngology
- Pediatric Surgery
- Plastic & Reconstructive Surgery
- Podiatry

- Urology

**Intended Use:**

The OmniGuide BeamPath® FELS 25A, $CO_2$ Laser System intended to be used in conjunction with the OmniGuide BeamPath Adapter and the OmniGuide BeamPath fiber and is intended to be used for the incision, excision, ablation, vaporization and coagulation of body soft tissues including intra-oral tissues.

**Summary of Technological Characteristics:**

The device is a 30 watt maximum power $CO_2$ laser, emitting wavelength of 10.6 μm. The System incorporates an adapter that allows the connection to $CO_2$ waveguide fibers such as the OmniGuide BeamPath WaveGuide Fiber, to transmit the laser energy to the surgical site.

**Performance Data:**

Non-clinical Performance Data: The OmniGuide BeamPath® FELS 25A, $CO_2$ Laser System performance characteristics have been evaluated through testing and analysis of laser power output and beam quality. This type of testing complies with the respective section of the FDA Guidance on the Content and Organization of a Premarket Notification for a Medical Laser (1995) and is similar to the predicate device tests. The performance of OmniGuide BeamPath® FELS 25A, $CO_2$ Laser System and related parameters of the predicate device are the same.

Clinical Performance Data: Formal clinical trials were not deemed necessary as the device is using the same technology and intended use as predicate device.

**Conclusions Drawn from Tests and Analysis:** The intended use and major performance parameters of the OmniGuide BeamPath® FELS 25A, $CO_2$ Laser System are equivalent to the characteristics of above mentioned legally marketed device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

OmniGuide, Inc.
% Regulatory Technology Services, LLC
Mr. Mark Job
1394 25th Street, Northwest
Buffalo, Minnesota 55313

OCT 2 9 2009

Re: K093251
Trade/Device Name: OmniGuide BeamPath® FELS 25A, $CO_2$ Laser System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: October 15, 2009
Received: October 16, 2009

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): Not yet assigned K093251

Device Name: OmniGuide BeamPath® FELS 25A, $CO_2$ Laser System

Indications for Use:

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- Podiatry
- Urology

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. P. Ogden for mxm

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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